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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,273	10/12/2001	Hanry Yu	004814.00003	8862

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EXAMINER	
LANKFORD JR, LEON B	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/975,273	YU ET AL.	
	Examiner	Art Unit	
	Leon Lankford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to microcapsule Type II, classified in class 427, subclass 213.34.

II. Claims 11-13, drawn to a method of preparing microcapsule Type II, classified in class 427 subclass 213.34

III. Claim 26, drawn to a method of making a bioartificial assist liver device using microcapsule Type II, classified in class 435, subclass 289.1.

IV. Claim 29, drawn to a bioartificial liver assist device comprising microcapsule Type II, classified in class 435, subclass 289.1.

V. Claim 32, drawn to a method of preparing cells from microcapsule Type II for imaging study, classified in class 435, subclass 382.

VI. Claim 33, drawn to a method of preparing cells from microcapsule Type II for transplant, classified in class 435, subclass 382.

VII. Claim 34, drawn to a method of analyzing cells from microcapsule Type II, classified in class 435, subclass 382.

VIII. Claims 5-6, drawn to a microcapsule Type III, classified in class 427, subclass 213.34.

IX. Claims 14-15 drawn to a method of preparing microcapsule Type III, classified in class 427, subclass 213.34.

X. Claim 27, drawn to a method of making a bioartificial liver assist device using microcapsule Type III, classified in class 435, subclass 289.1.

XI. Claim 30, drawn to a bioartificial liver assist device comprising microcapsules Type III, classified in class 435, subclass 289.1.

XII. Claims 7-9, drawn to a microcapsule Type IV, classified in class 427, subclass 213.34.

XIII. Claims 16-17, drawn to a method of preparing microcapsule Type IV, classified in class 427, subclass 213.34.

XIV. Claim 28, drawn to method of making a bioartificial liver device using microcapsule Type IV, classified in class 435, subclass 289.1.

XV. Claim 31, drawn to a bioartificial liver assist device comprising microcapsule Type IV, classified in class 435, subclass 289.1.

XVI. Claims 19-25, drawn to a multi-layer microcapsule, classified in class 427, subclass 213.34.

XVII. Claim 18, drawn to a method of culturing cells, classified in class 435, subclass 382.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, VII, XII and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the microcapsules of Inventions I, VIII, XII, and XVI are structurally and physically different. They constitute significantly different physical and chemical components and therefore distinct. For example, the microcapsule of Invention I comprises an outer shell that consists of two layers, one layer of a biopolymer and

one layer of oppositely charged biocompatible synthetic polyelectrolytes. None of the other microcapsules have an outer shell comprising two defined layers. Invention VIII comprises only two layers, an inner extracellular matrix, and an outer shell comprising a macroporous exoskeleton. None of the other microcapsules utilize the macroporous skeleton as the outermost shell. Invention XII comprises a three-layered microcapsule, where a synthetic polymer outer shell surrounds the macroporous exoskeleton. Invention XII also has an inner extracellular matrix that consists of two defined layers, a biopolymer inner layer, and a biocompatible synthetic polyelectrolyte outer layer. None of the other microcapsules combine the double inner layer with an intermediate macroporous exoskeleton and a single layered outer shell. Finally, Invention XVI comprises a multi-layered microcapsule with four distinct layers. The third layer is an exoskeleton comprised of ceramic sol, the other microcapsules only have macro-porous exoskeletons, and none have ceramic sol exoskeletons. Therefore because the microcapsules of Inventions I, VIII, XII, XVI are all chemically and structurally different from one another, they are deemed patentably distinct and restriction is required.

3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed in Invention II can be used to make a materially different product, such as vehicles for the delivery of chemicals in orally administered drugs.

Microcapsule Type II (Invention I)

4. Invention I is related to Inventions III, V, VI, VII, and XVII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed in Invention I can be used in a materially different process then those described in Inventions III-VIII, such as implanting the cell containing microcapsule in diabetic patients to help with insulin production.

5. Inventions I, VII, XII and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions I and IV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Invention I can be used in materially different methods, such as in developing cell cultures. Further, Invention IV can be accomplished by growing hepatocytes in any suitable matrix.

6. Inventions I, VII, XII and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions II, III, V, VI, VII, and XVII are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and achieve different goals. Invention II is directed to making the microcapsules, though other inventions use the microcapsules, they do not make use of the methods of producing them. Invention III requires packaging microcapsules in a bioreactor, which is not required by any of the other groups. Invention V requires imaging the cells using microscopy,

which is not required by any of the other groups. Invention VI requires harvesting the cells and coupling them to a scaffold for transplantation, which is not required by any of the other groups. Invention VII requires analyzing cells from a biopsy sample, which is not required by any other group. Invention XVII requires rupturing the microcapsules to recover the cells for culture; none of the other groups have this goal. Therefore, a search and examination of all five methods in one patent application would result in an undue burden, since the searches for the five methods are not co-extensive, the classification is different, and the subject matter is divergent.

7. The product of Invention IV is separate and distinct from the methods of Inventions II, IV, VI, VII, and XVII, wherein the product may neither be made by nor used in the methods. Accordingly, restriction is proper.

8. Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case a bioartificial liver assist device can be made by growing hepatocytes in any suitable matrix and transplanting it into the liver.

Microcapsule Type III (Invention VIII)

9. Inventions VIII and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed in Invention IX can be used to make a materially different

product then Invention VIII, such as vehicles for the delivery of chemicals in orally administered drugs.

10. Invention VIII is related to Inventions X and XVII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed in Invention VIII can be used in a materially different process then those described in Invention X or XVII, such as implanting the cell containing microcapsule in diabetic patients to help with insulin production.

11. Inventions I, VII, XII and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions VIII and XI are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Invention VIII can be used in materially different methods, such as in developing cell cultures. Further, Invention XI can be accomplished by growing hepatocytes in any suitable matrix.

12. Inventions I, VII, XII and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions IX, X, and XVII are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and

achieve different goals. Invention IX is directed to making the microcapsule, though the other invention can use the microcapsules, it does not make use of the methods of producing them. Invention X requires packaging microcapsules in a bioreactor, which is not required by any of the other groups. Invention XVII requires rupturing the microcapsule to recover the cells, which is not required by any of the other groups. Therefore the methods are considered distinct inventions.

13. Inventions X and XI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case a bioartificial liver assist device can be made by growing hepatocytes in any suitable matrix and transplanting it into the liver.

14. The product of Invention XI is separate and distinct from the methods of Inventions IX and XVII, wherein the product may neither be made by nor used in the methods. Accordingly, restriction is proper.

Microcapsule IV (Invention XII)

15. Inventions XII and XIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed in Invention XIII can be used to make a materially different product then Invention XII, such as vehicles for the delivery of chemicals in orally administered drugs.

16. Invention XII is related to Inventions XIV and XVII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed in Invention XII can be used in a materially different process then those described in Inventions XIV or XVII, such as implanting the cell containing microcapsule in diabetic patients to help with insulin production.

17. Inventions I, VII, XII and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions XII and XV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Invention XII can be used in materially different methods, such as in developing cell cultures. Further, Invention XV can be accomplished by growing hepatocytes in any suitable matrix.

18. Inventions I, VII, XII and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions XIII, XIV, and XVII are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and achieve different goals. Invention IX is directed to making the microcapsule, though the other invention can use the microcapsules, it does not make use of the methods of

producing them. Invention X requires packaging microcapsules in a bioreactor, which is not required by any of the other groups. Invention XVII requires rupturing the microcapsule to recover the cells, which is not required by any of the other groups. Therefore the methods are considered distinct inventions.

19. Inventions XIV and XV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case a bioartificial liver assist device can be made by growing hepatocytes in any suitable matrix and transplanting it into the liver.

20. The product of Invention XV is separate and distinct from the methods of Inventions XIII and XVII, wherein the product may neither be made by nor used in the methods. Accordingly, restriction is proper.

Multi-layered Microcapsule (Invention XVI)

21. Invention XVI is related to Invention XVII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed in Invention XVI can be used in a materially different process then those described in Invention XVII, such as implanting the cell containing microcapsule in diabetic patients to help with insulin production.

22. Because the microcapsules have been deemed distinct from one another, and the methods of making and methods of using have been shown to be distinct from their respective product, it is clear that the methods and uses are not transferable to the different microcapsules.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, which ever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in the light of *In re Ochiai, In re*

Brouwer and 34 U.S.C § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

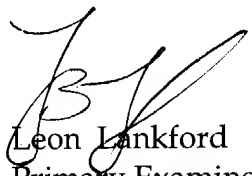
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1651

LBL